EMA drug utilisation study of cyproterone-ethinylestradiol products

First published: 25/03/2013

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/14145

EU PAS number

EUPAS3718

Study ID

14145

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany
- ☐ United Kingdom

Study description

To aim of the study is to analyse drug utilisation of cyproterone/ethinylestradiol products in electronic health record databases from the UK, France and Germany. The study period is 2002-2011. The study period was selected in order to have all three databases collecting data as well as completeness of data in each year.For each of the three databases all patients receiving cyproterone/ethinylestradiol during 2002-2011 have been identified. The German database contains the medical records of private specialists, here the data from internists, gynaecologist and dermatologists will be used, while the rest will be excluded. For the two other countries, the databases contain data from General Practitioners.Co-prescribing of any of the 2nd, 3rd, and 4th generation CHC (Combined Hormonal Contraceptives) as well as isotretinoin will be investigated.Co-prescribing is defined as any prescription done within 30 days before and after a prescription of cyproterone/ethinylestradiol. The prescribing has to be done by the same physician/General Practitioner practice.The results will be presented as percentages of the study populations of cyproterone/ethinylestradiol users.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Kristian Svendsen

Study contact

kristian.svendsen@ema.europa.eu

Primary lead investigator

Kristian Svendsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/02/2013

Actual: 15/03/2013

Study start date

Planned: 05/03/2013

Actual: 05/03/2013

Date of final study report

Planned: 22/03/2013

Actual: 22/03/2013

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To study the drug utilisation of cyproterone/ethinylestradiol in Electronic Health Record databases from UK, France and Germany.

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

CYPROTERONE

ETHINYLESTRADIOL

Medical condition to be studied

Contraception

Population studied

Short description of the study population

Female patients receiving cyproterone/ethinylestradiol during 2002-2011.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

80000

Study design details

Data analysis plan

Descriptive analyses only

Documents

Study, other information

EMA Analysis of IMS data on cyproterone-EE drug utilisation.pdf(756.07 KB)

Data management

Data sources

Data source(s), other

LifeLink EMR FR, IMS Disease Analyzer Germany

Data sources (types)

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No